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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,547	03/23/2000	Randall S. Kent	JAO 28796.02	3851

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EXAMINER
MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
1744	10

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

A510

Office Action Summary	Application No.	Applicant(s)	
	09/533,547	KENT ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,30-32,34 and 35* is/are rejected.

7)☒ Claim(s) *29 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 13-15, 18, 20-22, 25-28, 30, 31, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al ("Microbiological Studies on Drugs and Their Raw Materials").

Sakai et al teaches the sterilization of enzymes containing glucose and/or lactose (food ingredients) and L-cysteine, an anti-oxidant protectant. The enzyme preparations are sterilized in lyophilized form with gamma radiation at a dose rate of 3.45 rad/hr (0.345 kGy/hr). Enzymes are a proteinaceous material and both glucose and lactose are both carbohydrates. See pages 1130-1131.

3. Claims 1, 2, 4-8, 14, 19, 21, 22, 25-28, 30, 32, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Chanderkar et al ("The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation").

Chanderkar et al teaches sterilization of fibrinogen in lyophilized form. The preparation is irradiated by gamma radiation with a dose rate of 12,500 R/min (7.5 kGy/hr). Potassium iodide, an electron scavenger, is added as a protectant. See pages 283-284.

4. Claims 1, 2, 4-6, 9, 14, 18, 20-23, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Baquey et al ("Radiosterilization of albuminated polyester prostheses").

Baquey et al teaches the use of gamma radiation to sterilize albumin coated upon polyester. The samples were lyophilized and irradiated at a dose rate of 2600 rad/min in a low oxygen atmosphere (1.56 kGy/hr). See page 186.

5. Claims 1, 2, 5, 10, 14, 19, 22, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Field et al ("Susceptibility of Scrapie Agent to Ionizing Radiation").

Field et al teaches the sterilization of brain tissue that has been lyophilized. The tissue is irradiated with gamma radiation at a dose rate of 43,000 rad/min (25.8 kGy/hr).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4, 6, 11, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al.

Sakai et al teaches generally the sterilization of "biological materials" and specifically teaches the sterilization of an enzyme, trypsin. Although trypsin is not a component of blood, blood does contain other enzymes. Thus, it would have been obvious to one of ordinary skill in the art to use the method of Sakai et al to sterilize other enzymes and biological materials since the method has been shown to be effective and since Sakai et al discloses that "the biological activities of these drugs are not impaired and undesirable byproducts are not formed."

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al or Chanderkar et al or Field et al as applied to claim 1 above, and further in view of Horowitz et al (U.S. Patent No. 5,981,163).

The references *supra* teach lyophilization of the product, but do not teach that the solvent removed is an organic solvent. Horowitz et al, however, teaches that it is known in the art to combine a radiation sterilization step with another sterilization step such as treatment with an organic (lipid) solvent. See col.7, line 66 to col.8, line 7. Since it would have been obvious to first treat the product with a lipid solvent to inactivate viruses, it would have been further obvious to remove the solvent before irradiation, in the manner of Sakai et al, Chanderkar et al, or Field et al.

11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baquey et al.

In order to achieve a low oxygen atmosphere, Baquey et al uses an inert gas nitrogen. Although Baquey et al doesn't disclose argon as the inert gas, it is deemed obvious to substitute one inert gas for another in the method of Baquey et al.

Allowable Subject Matter

12. Claims 29 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record Sakai et al, Chanderkar et al, Baquey et al, and Field et al, all fail to teach the addition of a sensitizer to the product before radiation and also fail to teach or suggest the particular stabilizer, as set for the claim 33.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
February 24, 2003